

Application No.: 10/021,294

Docket No.: CTCH-P01-014

**IN THE CLAIMS**

1-4. (cancelled)

5. (previously presented) A composition comprising:

a cyclodextrin-containing polymer,

a therapeutic agent, and

a complexing agent, comprising:

at least one guest moiety that forms an inclusion complex with a host moiety of said cyclodextrin-containing polymer, wherein the guest moiety is selected from adamantyl, naphthyl, cholesterol, and combinations thereof, and

at least one polymer portion that increases solubility and/or imparts stabilization relative to a composition of the cyclodextrin-containing polymer and therapeutic agent alone;

wherein the cyclodextrin-containing polymer, the therapeutic agent, and the complexing agent are separate molecules.

6. (previously presented) A composition of claim 5, wherein said therapeutic agent is selected from an antibiotic, a steroid, a polynucleotide, small molecule pharmaceutical, a virus, a plasmid, a peptide, a peptide fragment, a chelating agent, a biologically active macromolecule, and mixtures thereof.

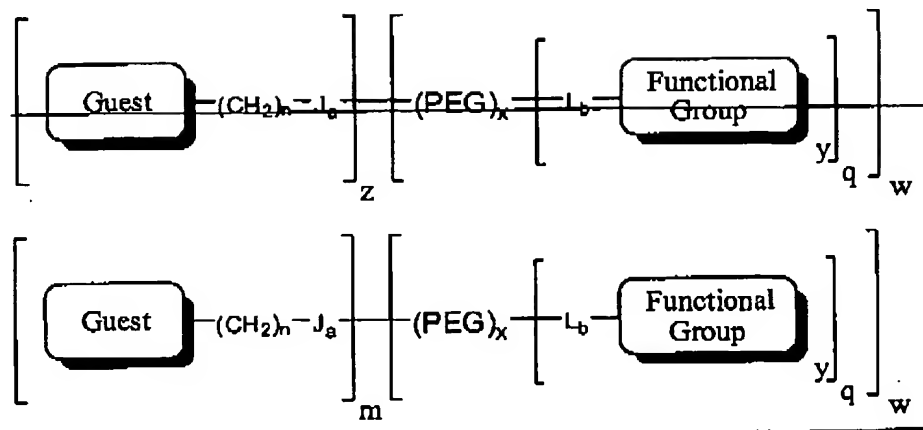
7. (previously presented) A composition of claim 6, wherein said therapeutic agent is a polynucleotide.

8-11. (cancelled)

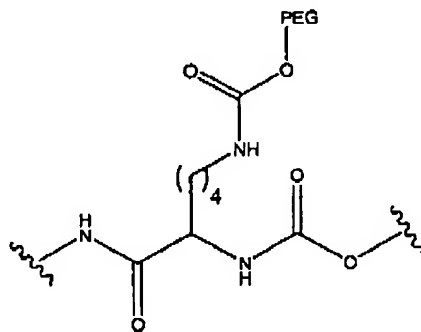
12. (currently amended) A composition of claim 5, wherein the complexing agent is a compound of the formula:

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wherein

J is  $-\text{NH}-$ ,  $-\text{C}(=\text{O})\text{NH}-\text{CH}_2)_d-$ ,  $-\text{NH}-\text{C}(=\text{O})-(\text{CH}_2)_d-$ ,  $-\text{CH}_2\text{SS}-$ ,  $-\text{C}(=\text{O})\text{O}-(\text{CH}_2)_e-\text{O}-\text{P}(=\text{O})(\text{O}-$  $(\text{CH}_2)_e-\text{Y})\text{O}-$ ,

, a peptide or polypeptide residue, or

 $-\text{NH}-(\text{C}=\text{O})-\text{CH}(\text{R}^1)-\text{NH}-(\text{C}=\text{O})-\text{CH}(\text{R}^1)-\text{NH}-$ ;

Y is an additional host-guest functionality;

 $\text{R}^1$  is  $-(\text{CH}_2)_a-\text{CO}_2\text{H}$ , an ester or salt thereof; or  $-(\text{CH}_2)_a-\text{CONH}_2$ ;PEG is  $-\text{O}(\text{CH}_2\text{CH}_2\text{O})_z-$ , where z varies from 2 to 500;L is H,  $-\text{NH}-$ ,  $-\text{NH}-(\text{C}=\text{O})-(\text{CH}_2)_e-(\text{C}=\text{O})-\text{CH}_2-$ ,  $-\text{S}(=\text{O})_2-\text{HC}=\text{CH}-$ ,  $-\text{SS}-$ ,  $-\text{C}(=\text{O})\text{O}-$ , or a carbohydrate residue;

a is 0 or 1;

b is 0 or 1;

d ranges from 0 to 6;

e ranges from 1 to 6;

m ranges from 1 to 5;

n ranges from 0 to 6;

q ranges from 1 to 5;

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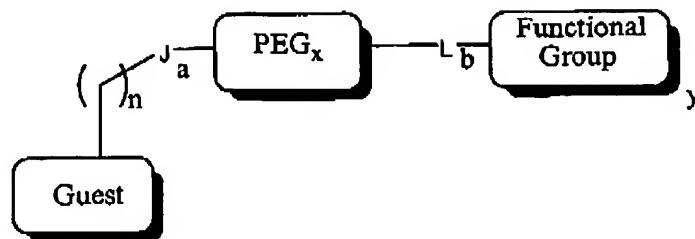
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w ranges from 1 to 5;

y is 1; and

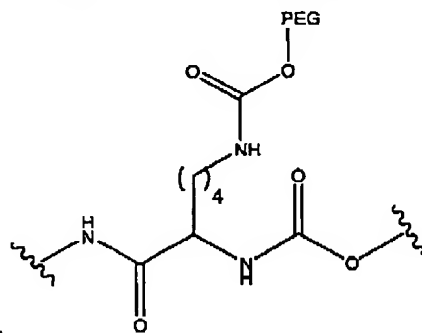
x is 0 or 1.

13. (previously presented) A composition of claim 5, wherein the complexing agent is a compound of the formula:



wherein

J is  $-\text{NH}-$ ,  $-\text{C}(=\text{O})\text{NH}-(\text{CH}_2)_d-$ ,  $-\text{NH}-\text{C}(=\text{O})-(\text{CH}_2)_d-$ ,  $-\text{CH}_2\text{SS}-$ ,  $-\text{C}(=\text{O})\text{O}-(\text{CH}_2)_e-\text{O}-\text{P}(=\text{O})(\text{O}-$

 $(\text{CH}_2)_e-\text{Y})\text{O}-$ ,

, a peptide or polypeptide residue, or

$-\text{NH}-(\text{C}=\text{O})-\text{CH}(\text{R}^1)-\text{NH}-(\text{C}=\text{O})-\text{CH}(\text{R}^1)-\text{NH}-$ ;

Y is an additional host-guest functionality;

$\text{R}^1$  is  $-(\text{CH}_2)_3-\text{CO}_2\text{H}$ , an ester or salt thereof; or  $-(\text{CH}_2)_3-\text{CONH}_2$ ;

PEG is  $-\text{O}(\text{CH}_2\text{CH}_2\text{O})_z-$ , where z varies from 2 to 500;

L is H,  $-\text{NH}-$ ,  $-\text{NH}-(\text{C}=\text{O})-(\text{CH}_2)_6-(\text{C}=\text{O})-\text{CH}_2-$ ,  $-\text{S}(=\text{O})_2-\text{HC}=\text{CH}-$ ,  $-\text{SS}-$ ,  $-\text{C}(=\text{O})\text{O}-$ , or a carbohydrate residue;

a is 0 or 1;

b is 0 or 1;

d ranges from 0 to 6;

e ranges from 1 to 6;

n ranges from 0 to 6;

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y is 1; and

x is 0 or 1.

14. (previously presented) A composition of claim 5, wherein the complexing agent further comprises a group selected from a ligand, a nuclear localization signal, an endosomal release peptide, an endosomal release polymer, or a membrane permeabilization agent.

15. (previously presented) A composition of claim 5, wherein the polymer portion increases the solubility of the composition under biological conditions relative to a composition of the cyclodextrin-containing polymer and therapeutic agent alone.

16. (previously presented) A composition of claim 5, wherein the polymer portion stabilizes the composition under biological conditions relative to a composition of the cyclodextrin-containing polymer and therapeutic agent alone.

17. (previously presented) A composition of claim 5, wherein the complexing agent further comprises a therapeutic agent reversibly bound to the complexing agent.

18. (previously presented) A composition of claim 5, wherein the complexing agent further comprises a spacer group.

19-22. (cancelled)

23. (previously presented) A composition of claim 5, wherein at least one polymer portion of the complexing agent comprises PEG or derivatives thereof.

24-26. (cancelled)

27. (previously presented) A composition of claim 5, wherein the cyclodextrin-containing polymer comprises one or more cyclodextrins in side chains of the cyclodextrin-containing polymer.

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28. (previously presented) A composition of claim 5, wherein the cyclodextrin-containing polymer comprises a linear cyclodextrin-containing polymer wherein cyclodextrin moieties are present in the backbone of the polymer.

29. (cancelled)

30. (previously presented) A composition comprising:

a cyclodextrin-containing polymer,

a therapeutic agent, and

a complexing agent, comprising:

at least one functional group,

at least one guest moiety that forms an inclusion complex with a host moiety of said

cyclodextrin-containing polymer, wherein the guest moiety is selected from

adamantyl, naphthyl, cholesterol, and combinations thereof, and

at least one polymeric spacer group;

wherein the cyclodextrin-containing polymer, the therapeutic agent, and the complexing agent are separate molecules.

31. (previously presented) A composition of claim 30, wherein said therapeutic agent is selected from an antibiotic, a steroid, a polynucleotide, small molecule pharmaceutical, a virus, a plasmid, a peptide, a peptide fragment, a chelating agent, a biologically active macromolecule, and mixtures thereof.

32. (previously presented) A composition of claim 31, wherein said therapeutic agent is a polynucleotide.

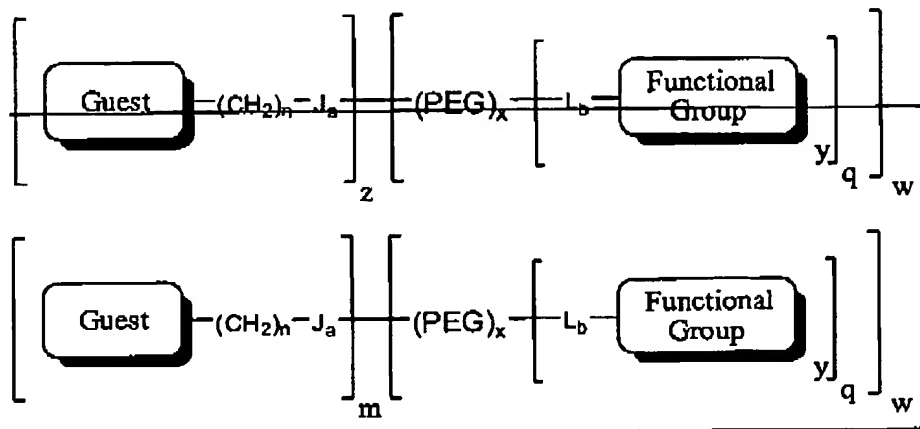
33. (cancelled)

34. (previously presented) A composition of claim 30, wherein at least one spacer group of the complexing agent comprises PEG or derivatives thereof.

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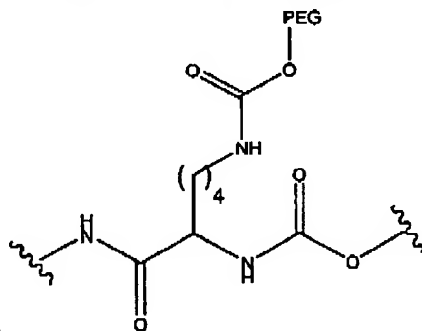
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35. (currently amended) A composition of claim 34, wherein the complexing agent is a compound of the formula:



wherein

J is  $-\text{NH}-$ ,  $-\text{C}(=\text{O})\text{NH}-\text{CH}_2)_d-$ ,  $-\text{NH}-\text{C}(=\text{O})-(\text{CH}_2)_d-$ ,  $-\text{CH}_2\text{SS}-$ ,  $-\text{C}(=\text{O})\text{O}-(\text{CH}_2)_e-\text{O}-\text{P}(=\text{O})(\text{O}-$



$(\text{CH}_2)_e-\text{Y})\text{O}-$ ,

, a peptide or polypeptide residue, or

$-\text{NH}-(\text{C}=\text{O})-\text{CH}(\text{R}^1)-\text{NH}-(\text{C}=\text{O})-\text{CH}(\text{R}^1)-\text{NH}-$ ;

Y is an additional host-guest functionality;

$\text{R}^1$  is  $-(\text{CH}_2)-\text{CO}_2\text{H}$ , an ester or salt thereof; or  $-(\text{CH}_2)_d-\text{CONH}_2$ ;

PEG is  $-\text{O}(\text{CH}_2\text{CH}_2\text{O})_x-$ , where z varies from 2 to 500;

L is H,  $-\text{NH}-$ ,  $-\text{NH}-(\text{C}=\text{O})-(\text{CH}_2)_e-(\text{C}=\text{O})-\text{CH}_2-$ ,  $-\text{S}(=\text{O})_2-\text{HC}=\text{CH}-$ ,  $-\text{SS}-$ ,  $-\text{C}(=\text{O})\text{O}-$ , or a carbohydrate residue;

a is 0 or 1;

b is 0 or 1;

d ranges from 0 to 6;

e ranges from 1 to 6;

m ranges from 1 to 5;

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n ranges from 0 to 6;

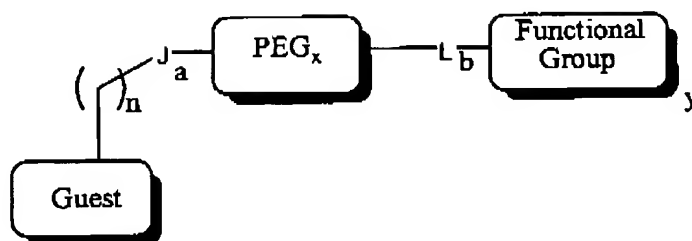
q ranges from 1 to 5;

w ranges from 1 to 5;

y is 1; and

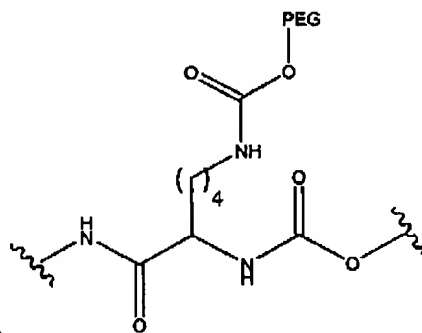
x is 1.

36. (previously presented) A composition of claim 34, wherein the complexing agent is a compound of the formula:



wherein

J is  $-\text{NH}-$ ,  $-\text{C}(=\text{O})\text{NH}-\text{CH}_2$ ,  $-\text{NH}-\text{C}(=\text{O})-(\text{CH}_2)_d-$ ,  $-\text{CH}_2\text{SS}-$ ,  $-\text{C}(=\text{O})\text{O}-(\text{CH}_2)_e-\text{O}-\text{P}(=\text{O})(\text{O}-$

 $(\text{CH}_2)_e-\text{Y})\text{O}-$ ,

, a peptide or polypeptide residue, or

$-\text{NH}-(\text{C}=\text{O})-\text{CH}(\text{R}^1)-\text{NH}-(\text{C}=\text{O})-\text{CH}(\text{R}^1)-\text{NH}-$ ;

Y is an additional host-guest functionality;

$\text{R}^1$  is  $-(\text{CH}_2)_a-\text{CO}_2\text{H}$ , an ester or salt thereof; or  $-(\text{CH}_2)_a-\text{CONH}_2$ ;

PEG is  $-\text{O}(\text{CH}_2\text{CH}_2\text{O})_z-$ , where z varies from 2 to 500;

L is H,  $-\text{NH}-$ ,  $-\text{NH}-(\text{C}=\text{O})-(\text{CH}_2)_e-(\text{C}=\text{O})-\text{CH}_2-$ ,  $-\text{S}(=\text{O})_2-\text{HC}=\text{CH}-$ ,  $-\text{SS}-$ ,  $-\text{C}(=\text{O})\text{O}-$ , or a carbohydrate residue;

a is 0 or 1;

b is 0 or 1;

d ranges from 0 to 6;

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e ranges from 1 to 6;

n ranges from 0 to 6;

y is 1; and

x is 1.

37. (previously presented) A composition of claim 30, wherein at least one functional group includes a group selected from a ligand, a nuclear localization signal, an endosomal release peptide, an endosomal release polymer, or a membrane permeabilization agent.

38. (previously presented) A composition of claim 30, wherein at least one functional group includes a moiety that increases the solubility of the composition under biological conditions relative to a composition of the cyclodextrin-containing polymer and therapeutic agent alone.

39. (previously presented) A composition of claim 30, wherein at least one functional group includes a moiety that stabilizes the composition under biological conditions relative to a composition of the cyclodextrin-containing polymer and therapeutic agent alone.

40. (previously presented) A composition of claim 30, wherein at least one functional group includes a therapeutic agent reversibly bound to the complexing agent.

41. (previously presented) A composition of claim 30, wherein the cyclodextrin-containing polymer comprises one or more cyclodextrins in side chains of the cyclodextrin-containing polymer.

42. (previously presented) A composition of claim 30, wherein the cyclodextrin-containing polymer comprises a linear cyclodextrin-containing polymer wherein cyclodextrin moieties are present in the backbone of the polymer.